

sub 1312
A2 cont
[octadecanoic] octadecadienoic acid alkyl ester and t10,c12-octadecanoic acid alkyl ester, and combinations thereof, and

in a second part comprising less than [5] two percent by aggregate weight of ester isomers selected from the group consisting of 8,10-[octadecanoic] octadecadienoic acid alkyl esters, 11,13-[octadecanoic] octadecadienoic acid alkyl esters, and trans,trans-[octadecanoic] octadecadienoic acid alkyl esters, and

in a third part comprising in the range of 0.1 to 0.5 percent phosphatidyl residue remaining after isomerization of said unrefined linoleic acid.

REMARKS

Claims 1-8 are at issue in the present application. The Claims stand rejected as follows:

- 1) Claims 1-3 are rejected under 35 U.S.C. §112, first paragraph as allegedly being nonenabled;
- 2) Claims 1-3 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite; and
- 3) Claims 1-8 stand rejected under 35 U.S.C. §103, as allegedly being obvious.

Applicants believe the present amendments and following remarks traverse the Examiner's rejection of the Claims.

1. The Claims are Enabled

Claims 1-3 are rejected under 35 U.S.C. §112, first paragraph as allegedly being nonenabled. Applicant's contend that the Examiner has not established a *prima facie* case of nonenablement. In making a nonenablement rejection, the burden is on the Examiner to make a *prima facie* case of nonenablement that is well grounded in scientific reasoning or evidence. *See In re Wright*, 27 U.S.P.Q.2d 1510 (Fed. Cir. 1993); *See also* MPEP §706.03 and §2164.04. This is because without a reason to doubt the truth of the statements made in the patent application, the application must be considered enabling (*Id.* at 1513).

The Examiner has not made properly reasoned and supported statements explaining failure to comply with 35 U.S.C. §112, paragraph 1. The Examiner states that "the

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the rations to which it pertains for all conventional ingredients in the invention commensurate in scope with these claims."

Furthermore, the Examiner states that "the person of ordinary skill in the art would not know how to make and use the claimed formulation to feed any animal species in 'typical' way for its age without undue experimentation." These are **conclusory** statements and not well grounded in scientific reasoning because the Examiner presents no reasoning as to why undue experimentation is required.

Furthermore, the Examiner states that "the examples do not recite all ingredients for all animals, e.g., humans, cats, fish, reptiles, or cattle." Applicants note that the Examiner admits that the Specification provides working examples for pig starter formulations, turkey grower and finisher formulations, and dry dog foods. In addition to these rations, the Specification also discloses a semi-moist dog food formula (Specification, page 24), starter and finisher rations for chickens (*i.e.*, broilers)(Specification, page 22), and pig grower and finisher rations (Specification, page 18-19). Furthermore, the Specification clearly contemplates that CLA alkyl esters can be added to **any** animal feed (See Specification, page 5, lines 25-33).

The Examiner's requirements are not commensurate with the patent laws. Even in unpredictable arts, one need not disclose each and every embodiment or species encompassed by a claim (*See In re Angstadt*, 190 U.S.P.Q. 214 (C.C.P.A. 1976)). As the *Angstadt* court stated "[t]he key word is 'undue' and not 'experimentation'" (*Id.* at 219) when enablement is at issue. Indeed, "a considerable amount of experimentation is permissible . . . if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed" (*Ex parte Jackson*, 217 U.S.P.Q. 804, 807 (Bd. App. 1982)). Therefore, Applicants are not required to disclose all rations for all animals. To do so would merely necessitate the rote recitation of additional rations, the formulations of which are well within the capabilities of those skilled in the art. Applicants have provided more than enough guidance to formulate a wide variety of feeds by way of example. Accordingly, the Examiner has misapplied the law and has not established a *prima facie* case of nonenablement. Therefore, the Claims should be passed to allowance.

2. The Claims are Definite

Claims 1-3 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The MPEP and Federal Circuit case law have made it clear that the definiteness of claim language must be analyzed, not in a vacuum, but in light of: 1) the content of the particular application's disclosure; 2) the teachings of the prior art; and 3) the claim interpretation that would be given by one possessing the ordinary level of skill in the art at the time the invention was made.¹ Applicants submit that application of this analysis leads to the conclusion that the Claims are definite.

The Examiner states that Applicants' use of the terms "conventional" and "typical" render Claims 1-3 indefinite. Applicants respectfully submit that a person of ordinary skill in the art would be able to interpret the claims and understand that the Claims are directed to any animal feed containing CLA alkyl esters of the claimed isomer composition. Nevertheless, in order to further the business interests of the Applicants, and without acquiescing to the Examiner's arguments, and while reserving the right to prosecute the Claims as originally drafted, Claim 1 has been amended to refer simply to animal feed. Therefore, Applicant's respectfully request that the indefiniteness rejection be removed and the Claims passed to allowance.

3. Examiner has not Established *Prima Facie* Case of Obviousness for Claims

A *prima facie* case of obviousness requires the Examiner to cite a combination of references which (a) disclose the elements of the claimed invention, (b) suggests or motivates one of skill in the art to combine those elements to yield the claimed combination, and (c) provides a reasonable expectation of success should the claimed combination be carried out. Failure to establish any one of the these three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles Applicant to allowance of the claims in issue. See, e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990). The Examiner has failed to establish a *prima facie* case of obviousness because the

¹ MPEP §2173.02, See also *In re Marosi*, 218 USPQ 289 (Fed. Cir. 1983); *Rosemount, Inc. v. Beckman Instruments, Inc.*, 221 USPQ 1 (Fed. Cir. 1984); and *W.L. Gore & Associates, Inc. v. Garlock, Inc.* 220 USPQ 303 (Fed. Cir. 1983).

combined references do not teach each element of the Claims and because the Examiner has not established a reasonable expectation of success.

A. The Combined References Do Not Teach Each Element of the Claims

The cited references do not teach each element of the Claims. The Examiner admits that "Cook is silent as to the amount of additional octadecadienoic acids in the compositions, specifically the 8,10 and 11,13 octadecadienoic acids (Office Action, page 4)." The Examiner goes on to state that "since the preferred amounts in applicants claims require less than 5 percent, this amount includes zero" (Office Action, page 4).

Applicants submit that the Cook *et al.* patents do not teach each element of the Claims because Cook *et al.* do not teach CLA compositions with less than 2% of the 8,10 and 11,13 isomers. The fact that the Cook *et al.* patents are silent as to the composition of their CLA cannot be relied upon to prove that the compositions may have low levels of certain isomers. Apparently, the Examiner is attempting make an "anticipation by inherency" type argument. The Federal Circuit has explained the standard for determining inherency:

Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient. *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268-69 (Fed. Cir. 1991).

The Examiner has not met this standard. The methods employed by Cook *et al.* could and often do result in compositions with greater than the claimed amounts of the 8,10 and 11,13 isomers. Conjugation of linoleic acid by known methods results in the formation of a variety of CLA isomers. Christie *et al.*, *JAACS*, 74(11): 1231 (1997)(Attached at Tab A), examined samples of commercially available CLA, most of which were produced by alkali isomerization. These samples were found to contain significant levels of contaminating isomers. In fact, one sample contained 14% 8,10 isomer and 24% 11,13 isomer. Christie *et al.* concluded that most samples of CLA contain 8,10 and 11,13 isomers. Furthermore, they stated that "[i]t is important that those who produce these materials and use them for research purposes appreciate the complex nature of their products."

The Examiner's attention is also directed to Sugano *et al.*, "Conjugated Linoleic Acid Modulates Tissue Levels of Chemical Mediators and Immunoglobulins in Rats," *Lipids*, 33(5):521-27 (1998)(Attached at Tab B). Sugano prepared CLA from purified linoleic acid by a method similar to that utilized by Cook. Sugano discloses that their CLA contained 18.6% trans-trans isomers and 13.7% other isomers in addition to the c9,t11 and t10,c12 isomers.

As can be seen, the actual composition of the Cook *et al.* CLA cannot be ascertained with certainty. Accordingly, the Cook *et al.* patents do not teach an element of the Claims because the amounts of 8,10 and 11,13 isomers are not known. Therefore, a *prima facie* case of obviousness has not been established and the Claims should be passed to allowance.

B. Cited References do not Provide Reasonable Expectation of Success

The cited references do not provide a reasonable expectation of success for obtaining the claimed compositions. The Federal Circuit has held that "obvious to experiment" is not the standard for obviousness. *In re Dow Chemical*, 5 USPQ2d 1529, at 1532 (Fed. Cir. 1988). The Dow court made it very clear that one must determine whether "the prior art would have suggested to one of ordinary skill in the art that this process **should** be carried out and **would** have a reasonable likelihood of success, viewed in light of the prior art." *Id.* at 1531 (Emphasis added).

Applicants submit that one skilled in the art would not believe that a reasonable expectation exists for utilizing the methods of the present invention to obtain the claimed CLA composition. As detailed in the Specification, optimization of reaction conditions was required to obtain a CLA composition characterized in containing low amounts of 8,10 and 11,13 isomers (*See* Examples 1-3). This realization was only reached after empirical experimentation. As shown in Example 1, aqueous alkali isomerization generally results in the production of substantial amounts of the 11,13 isomer, with both percent conjugation and percent of 11,13 isomer increasing with increasing temperature and pressure. Examples 2 and 3 describe the optimization of reaction conditions and reagents to produce high levels of conjugation while avoiding the production of substantial amounts of the 8,10 and 11,13 isomers.

As stated by the *Dow* court, the prior art must suggest that the invention "should be carried out" and would have a reasonable expectation of success. Rejections based on an "obvious to try" standard are not proper. The Federal Circuit has given some examples of what constitutes an "obvious to try" modification based on the prior art. See *In re O'Farrell*, 7USPQ2d 1673 (Fed. Cir. 1988). The *O'Farrell* court stated that in some cases,


"what was obvious to try was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art only gave general guidance as to the particular form of the claimed invention or how to obtain it." *Id.* at 903 (Citations omitted).

This situation is analogous to the present invention. The Examiner has apparently improperly applied an "obvious to try" rationale in rejecting the Claims. A person skilled in the art does not realize that invention **should** be carried out and **would** have a reasonable expectation of success. The success in making the claimed CLA compositions and feeds was only apparent after empirical experimentation. Therefore, the prior art does not provide a reasonable expectation of success for the present invention, and the Claims should be passed to allowance.

CONCLUSION

All grounds of rejection of the Office Action of October 18, 1999 having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the invention as claimed fully meets all requirements and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Examiner is encouraged to call Mitchell Jones collect at (608) 298-3000.

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